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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/068,804	05/14/1998	SAMUEL I. MILLER	00786/292002	2704

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FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/02/2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/068,804

Applicant(s)

MILLER, SAMUEL I.

Examiner

Padmavathi v Baskar

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 18 and 46-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-48, 52-54, 58-60, 64-66, 70- 72, 76-78 and 82 -83, 87, 90 and 92-95 is/are rejected.
- 7) ☒ Claim(s) 49-51, 55-57, 61-63, 67-69, 73-75, 79-81, 84-86, 88-89 and 91 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 26.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1645

DETAILED ACTION

1. Applicant's response to restriction filed on 7/02/02 (paper # 32) is acknowledged. Upon further review of the prosecution of the application, the examiner has withdrawn the restriction requirement and examining all the claims which are under prosecution. Claims 17-18, and 46-95 are pending in the application.

2. In view of the Declaration provided by Dr.S.Miller under 37C.F.R. 1.131 (EXHIBIT: E) and a copy of print out from Gene Bank data base ((EXHIBIT: F), the rejection under 35 U.S.C. 102 (a) as anticipated by Hermant et al 1995 (Mol. Biol 17:781-789) is withdrawn.

3. In view of the Declaration provided by Dr.S.Miller under 37C.F.R. 1.131 (EXHIBIT: E) and a copy of print out from Gene Bank data base ((EXHIBIT: F), the rejection under 35 U.S.C. 102 (a) as anticipated by Kaniga et al 1995 (J. Bact 177:3965-3971) is withdrawn.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 46, 52, 58, 64, 70, 76 and 82, is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Boehringer Mannheim Biochemicals (1991 Catalog page 557), Stratagene (1991 Product Catalog, page 66), Gibco BRL (Catalogue & Reference Guide 1992, page 292), Promega (1993/1994 Catalog, pages 90-91) or New England BioLabs (Catalog 1986/1987, pages 60- 62).

Art Unit: 1645

The claims are drawn to isolated nucleic acid molecule which hybridizes under conditions of hybridization in 50% formamide at 42°C and washing in 0.1X SSC at 65°C to a nucleic acid molecule consisting of the nucleotide sequence of SEQ.ID.NO: 1, 2, 3, 4, 13, 10 and 15.

Examiner is viewing the claims as drawn to any isolated nucleic acid molecule that hybridizes to a nucleic acid molecule consisting of the nucleotide sequence of SEQ.ID.NO: 1, 2, 3, 4, 13, 10 and 15.

Boehringer Mannheim Biochemicals (1991 Catalog page 557), Stratagene (1991 Product Catalog, page 66), discloses kits containing isolated packaged random 6-mer primers and random 9-mer primers. The random primer kits contain all possible 6 mer and 9 mer nucleic acid molecule which hybridizes with a nucleic acid molecule consisting of the nucleotide sequence of SEQ.ID.NO: 1, 2, 3, 4, 13, 10 and 15.

Gibco BRL (Catalogue & Reference Guide 1992, page 292), Promega (1993/1994 Catalog, pages 90-91) or New England BioLabs (Catalog 1986/1987, pages 60-62) each teach a wide variety of probes, primers over 10 nucleotides which hybridizes with a nucleic acid molecule consisting of the nucleotide sequence of SEQ.ID.NO: 1, 2, 3, 4, 13, 10 and 15. Therefore, the prior art nucleic acid molecule anticipated the claimed invention.

6. Claims 47-48, 53-54, 59-60, 65-66, 71- 72, 77-78, 83, 87 and 90-95 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Groisman et al 1993, The EMBOjournal 3779-3789 or

Claims are drawn to an isolated nucleic acid molecule comprising the nucleic acid sequence SEQ.ID.NO: 1, 2, 3, 4, 13, 10 and 15. Claims are also drawn to a nucleic acid sequence comprising a nucleotide molecule encoding a peptide comprising the amino acid

Art Unit: 1645

sequence SEQ.ID.NOS: 5, 6, 7, 8, 14, 12. Claims 87, 90-95 are drawn to isolated and purified molecules consisting essentially of SEQ.ID.NO: 1, 2, 3, 4, 13, 10, and 15.

Groisman et al 1993 disclose an isolated nucleotide molecule 6.4kb insert of RF319 (see page 3780, right column, last paragraph). Plasmid RF319 (see page 3786, left column, under materials and methods) comprises nucleic acid molecules that encode secretory proteins (Spa proteins).

The plasmid RF319 read on the claimed nucleic acid molecules as claims are not restricted to isolated molecules consisting of SEQ.ID.NO: 1, 2, 3, 4, 13, 10, 15 and the claimed nucleic acid molecules contain more than what is present in SEQ.ID.NO: 1, 2, 3, 4, 13, 10 and 15. Characteristics such as an isolated nucleic acid molecule SEQ.ID.NO: 1, 2, 3, 4, 13, 10 and 15 comprising the amino acid sequence 5, 6, 7, 8, 14, and 12 and isolated and purified molecules consisting essentially of SEQ.ID.NO: 1, 2, 3, 4, 13, 10, 15 are inherent in plasmid RF319. Therefore, the claims read on plasmid RF319. Since the Office does not have the facilities for examining and comparing applicant's product with the product, prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product, and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

7. Claims 47-48, 53-54, 59-60, 65-66, 71- 72, 77-78, 83, 87 and 90-95 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Collazo et al 1995, *Molecular Microbiology*, 15(1), 25-38.

Claims are discussed supra.

Collazo et al disclose Plasmid pYA2225 construct by cloning an isolated 7.3kb Sal fragment from pYa2219 in to pUC18. This plasmid carries a region of the *Inv* locus containing invasion gene, *invJ* gene (page 34, under plasmid construction).

Art Unit: 1645

The plasmid pYA2225 read on the claimed nucleic acid molecules as claims are not restricted to isolated molecules consisting of SEQ.ID.NO: 1, 2, 3, 4, 13, 10, 15 and the claimed nucleic acid molecules contain more than what is present in SEQ.ID.NO: 1, 2, 3, 4, 13, 10 and 15. Characteristics such as an isolated nucleic acid molecule SEQ.ID.NO: 1, 2, 3, 4, 13, 10 and 15 comprising the amino acid sequence 5, 6, 7, 8, 14, and 12 and isolated and purified molecules consisting essentially of SEQ.ID.NO: 1, 2, 3, 4, 13, 10, 15 are inherent in Plasmid pYA2225. Therefore, the claims read on Plasmid pYA2225. Since the Office does not have the facilities for examining and comparing applicant's product with the product, prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product, and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

8. Claims 49-51, 55-57, 61-63, 67-69, 73-75, 79-81, 84-86, 88-89 and 91 are objected to as being dependent upon a rejected base claim.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

9/28/03


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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